

**Sunovion Pharmaceuticals Inc.**

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## News Release

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### **Sunovion Pharmaceuticals Inc. Files Patent Infringement Lawsuits Regarding Latuda<sup>®</sup>**

**Marlborough, Mass., January 14, 2015** – Sumitomo Dainippon Pharma Co., Ltd. (“Sumitomo Dainippon Pharma”) and its U.S. subsidiary, Sunovion Pharmaceuticals Inc. (“Sunovion”), jointly filed patent infringement lawsuits on January 14, 2015 in the U.S. District Court for the District of New Jersey against Emcure Pharmaceuticals Limited, Emcure Pharmaceuticals USA, Inc., and InvaGen Pharmaceuticals Inc. regarding their submissions of Abbreviated New Drug Applications (“ANDAs”) for generic copies of Latuda<sup>®</sup> (lurasidone HCl tablets). The lawsuits allege infringement of Sumitomo Dainippon Pharma’s U.S. Patent No. 5,532,372 (“the ‘372 Patent”).

The ‘372 Patent is exclusively licensed to Sunovion in the United States, and Sunovion has been marketing lurasidone HCl tablets in the United States under the brand name LATUDA<sup>®</sup> since its launch in February 2011.

Due to the commencement of these lawsuits, the FDA approval of the ANDAs will be stayed at least until the earlier of April 28, 2018 (plus an additional six months thereafter if Sunovion is awarded a pediatric exclusivity extension) or the date of a district court decision finding the ‘372 Patent invalid, unenforceable, or not infringed. Should Sumitomo Dainippon Pharma and Sunovion successfully enforce the ‘372 Patent, ANDA approval should not occur at least until expiration of that patent on July 2, 2018 (plus an additional six months thereafter if Sunovion is awarded a pediatric exclusivity extension).

Sumitomo Dainippon Pharma and Sunovion believe that their patent position for LATUDA<sup>®</sup> is strong and they are prepared to vigorously protect their patent rights.

#### **About Sunovion Pharmaceuticals Inc. (Sunovion)**

Sunovion is a leading pharmaceutical company dedicated to discovering, developing and commercializing therapeutic products that advance the science of medicine in the Psychiatry & Neurology and Respiratory disease areas. Sunovion’s drug development program, together with its corporate development and licensing efforts, has yielded a portfolio of pharmaceutical products including Aptiom<sup>®</sup> (eslicarbazepine acetate), Latuda<sup>®</sup> (lurasidone HCl) tablets, Lunesta<sup>®</sup> (eszopiclone) tablets, Xopenex HFA<sup>®</sup> (levalbuterol tartrate) inhalation aerosol, Brovana<sup>®</sup> (arformoterol tartrate) inhalation solution, Omnaris<sup>®</sup> (ciclesonide) nasal spray, Zetonna<sup>®</sup> (ciclesonide) nasal aerosol and Alvesco<sup>®</sup> (ciclesonide) inhalation aerosol.

Sunovion, an indirect, wholly-owned U.S. subsidiary of Sumitomo Dainippon Pharma Co., Ltd., is headquartered in Marlborough, Mass. More information about Sunovion Pharmaceuticals Inc. is available at [www.sunovion.com](http://www.sunovion.com).

**About Sumitomo Dainippon Pharma Co., Ltd.**

Sumitomo Dainippon Pharma is a top-ten listed pharmaceutical company in Japan. Sumitomo Dainippon Pharma aims to produce innovative pharmaceutical products in the Psychiatry & Neurology area and the Oncology area, which have been designated as the focus therapeutic areas. Sumitomo Dainippon Pharma is based on the merger in 2005 between Dainippon Pharmaceutical Co., Ltd., and Sumitomo Pharmaceuticals Co., Ltd. Today, Sumitomo Dainippon Pharma has about 7,000 employees worldwide. Additional information about Sumitomo Dainippon Pharma is available through its corporate website at [www.ds-pharma.com](http://www.ds-pharma.com)

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